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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,562	07/06/2001	Katie Mary Binley	9192.16USWO	3021

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/19/2003 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/787,562	Binley et al.
Examiner	**Art Unit**
Shin-Lin Chen	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 9, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-15, 17-27, and 31* is/are pending in the application.

4a) Of the above, claim(s) *21-27* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-15, 17-20, and 31* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

It should be noted that examiner for the present application has been changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen.

Applicants' "Response to the Restriction Requirement" and amendment filed 12-9-02 have been entered. Claims 2, 5-7, 9-12, 19-27 and 31 have been amended. Claims 1-15, 17-27 and 31 are pending.

Upon further consideration of Applicants' response and the amended claims, the pending claims 1-15, 17-27 and 31 are re-restricted.

It should be noted that claims 21-27 are directed to polypeptide and depend on claim 1, however, claim 1 is directed to a polynucleotide. It is unclear what is intended to be claimed in claims 21-27. Thus, claims 21-27 can not be restricted and are withdrawn from consideration.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10, 12-15, 20 and 31, drawn to a polynucleotide comprising at least two hypoxia response element (HRE) having SEQ ID No. 1, 2 or 9, wherein the hypoxia-inducible factor (HIF) consensus binding sites within each of the two repeats are separated by a

spacer having SEQ ID No. 10 or 11, and a nucleic acid of interest (NOI) encoding HIF-1, and a method of producing a viral strain by introducing the polynucleotide of claim 2 into the genome of a virus.

Group II, claim(s) 1-8, 11-15, 20 and 31, drawn to a polynucleotide comprising at least two hypoxia response element (HRE) having SEQ ID No. 3, 4, or 5, wherein the hypoxia-inducible factor (HIF) consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID No. 10 or 11, and a nucleic acid of interest (NOI) encoding HIF-1, and a method of producing a viral strain by introducing the polynucleotide of claim 2 into the genome of a virus.

Group III, claim(s) 1-12, 14, 15, 17, 20 and 31, drawn to a polynucleotide comprising at least two hypoxia response element (HRE), wherein the hypoxia-inducible factor (HIF) consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID No. 10 or 11, and a nucleic acid of interest (NOI) encoding a cytotoxic polypeptide, and a method of producing a viral strain by introducing the polynucleotide of claim 2 into the genome of a virus.

Group IV, claim(s) 1-12, 14, 15, 18, 20 and 31, drawn to a polynucleotide comprising at least two hypoxia response element (HRE), wherein the hypoxia-inducible factor (HIF) consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID No. 10 or 11, and a nucleic acid of interest (NOI) encoding a polypeptide capable of converting a

precursor into a cytotoxic compound, and a method of producing a viral strain by introducing the polynucleotide of claim 2 into the genome of a virus.

Group V, claim(s) 1-12, 14, 15, 19, 20 and 31, drawn to a polynucleotide comprising at least two hypoxia response element (HRE), wherein the hypoxia-inducible factor (HIF) consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID No. 10 or 11, and a nucleic acid of interest (NOI) encoding a transcription factor, and a method of producing a viral strain by introducing the polynucleotide of claim 2 into the genome of a virus.

Group VI, claim(s) 1-12, 14, 15, 19, 20 and 31, drawn to a polynucleotide comprising at least two hypoxia response element (HRE), wherein the hypoxia-inducible factor (HIF) consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID No. 10 or 11, and a nucleic acid of interest (NOI) encoding a metabolic enzyme, and a method of producing a viral strain by introducing the polynucleotide of claim 2 into the genome of a virus.

Group VII, claim(s) 1-12, 14, 15, 19, 20 and 31, drawn to a polynucleotide comprising at least two hypoxia response element (HRE), wherein the hypoxia-inducible factor (HIF) consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID No. 10 or 11, and a nucleic acid of interest (NOI) encoding a proliferation-regulating protein, and a method of producing a viral strain by introducing the polynucleotide of claim 2 into the genome of a virus.

Group VIII, claim(s) 1-12, 14, 15, 19, 20 and 31, drawn to a polynucleotide comprising at least two hypoxia response element (HRE), wherein the hypoxia-inducible factor (HIF) consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID No. 10 or 11, and a nucleic acid of interest (NOI) encoding a heat shock protein, and a method of producing a viral strain by introducing the polynucleotide of claim 2 into the genome of a virus.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group 1 and II do not share common special technical feature because they are drawn to a polynucleotide having different HRE promoter sequences that differ chemically and structurally and have different functions: SEQ ID Nos. 1, 2 and 9 vs SEQ ID Nos. 3-5. Groups I, II and groups III-VIII do not share special technical feature because they are drawn to different products for different uses that require different special technical features: nucleic acid encoding HIF-1 (I and II), cytotoxic polypeptide (III), polypeptide capable of converting a precursor into a cytotoxic compound (IV), transcription factor (V), metabolic enzyme (VI), proliferation-regulating protein (VII), and heat shock protein (VIII). Thus, groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1.

Upon election of group I, further restriction is required. SEQ ID Nos. 1, 2 and 9 represent different HRE promoters having different chemical structure and biological functions, therefore, further election of **one SEQ ID No.** from the group consisting of SEQ ID Nos. 1, 2 and 9 is

required. Similarly, applicant is required to elect **one SEQ ID No.** from the group consisting of SEQ ID Nos. 10 and 11.

Upon election of group II, further restriction is required. SEQ ID Nos. 3-5 represent different HRE promoters having different chemical structure and biological functions, therefore, further election of **one SEQ ID No.** from the group consisting of SEQ ID Nos. 3-5 is required. Similarly, applicant is required to elect **one SEQ ID No.** from the group consisting of SEQ ID Nos. 10 and 11.

Upon election of groups III-VIII, further restriction is required. As discussed above, SEQ ID Nos. 1-5 and 9 represent different HRE promoters having different chemical structure and biological functions, therefore, further election of **one SEQ ID No.** from the group consisting of SEQ ID Nos. 1-5 and 9 is required. Similarly, applicant is required to elect **one SEQ ID No.** from the group consisting of SEQ ID Nos. 10 and 11.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.